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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,871	11/05/2003	Renfeng Guo	UM-08443	6716

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,871	GUO ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-28 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-28 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *101606*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 05/03/04 and 10/16/06.

Election

2) Acknowledgment is made of Applicants' election filed 10/16/06 in response to the restriction requirement mailed 09/13/06. Applicants have elected invention IV, claims 26-28 and 30, without traverse.

Status of Claims

3) Claims 1-25 have been canceled via the amendment filed 10/16/06.

Claim 29 has been canceled via the amendment filed 05/03/04.

Claim 30 has been amended via the amendment filed 10/16/06.

Claims 26-28 and 30 are pending and are under examination.

Information Disclosure Statement

4) Acknowledgment is made of Applicants' information disclosure statement filed 10/16/06. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

5) Acknowledgment is made of Applicants' Sequence Listing, which has been entered on 05/07/04.

Priority

6) The instant application claims priority to the provisional application 60/423,759, filed 11/05/02.

Specification

7) The instant specification is objected to for the following reason:

The drawings for Figures 2 and 3 include three panels, A, B and C. However, the 'Description of the Figures' on page 4 of the specification does not indicate the three panels. It is

suggested that Applicants replace the limitations 'Figure 2 shows' and 'Figure 3 shows' on page 4 of the specification with --Figures 2A to 2C show-- and --Figures 3A to 3C show-- respectively.

Double Patenting Rejection

8) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

9) Claims 26-28 and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 2 and 4-7 of the co-pending application 11/236,188. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claims 2 and 4-7 of the above-identified co-pending application falls within the scope of the above-identified instant claims. The method of treating sepsis in a human by providing an antibody specific to the recited C5a peptides and administering the same to a human to reduce at least one symptom of sepsis anticipates the instantly claimed method.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

10) Claims 26-28 and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of the U.S patent 6,866,845. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claimed in claims 1-4 of the U.S patent 6,866,845 is drawn to a method of treatment of

sepsis in a human subject comprising providing a therapeutic antibody composition specific to a C5a peptide and administering the therapeutic antibody composition to said subject to reduce at least one symptom and therefore, falls within the scope of the generic method claimed in the instant claims.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

11) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

12) Claim 28 is rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention

Claim 28 is vague and indefinite in the limitation 'small molecule'. The term 'small' is a relative term. How small a molecule must be to qualify as a 'small molecule' antagonist of the C5a receptor is unclear.

Rejection(s) under 35 U.S.C. § 102

13) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
> A person shall be entitled to a patent unless –
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14) Claims 26-28 are rejected under 35 U.S.C § 102(b) as being anticipated by Strachan *et al.* (*J. Immunol.* 164: 6560-6565, 2000 – Applicants' IDS).

Strachan *et al.* taught a method of treating symptoms of sepsis such as LPS-induced neutrophil adhesion, neutropenia, and cytokine expression by providing a new small molecule C5a receptor antagonist, AcF-[OPdChaWR] having acute anti-inflammatory properties, and administering the C5a receptor antagonist to rats with LPS-induced neutropenia. Strachan *et al.* taught that C5a is implicated as a pathogenic factor in sepsis and showed that a single dose of AcF-[OPdChaWR] significantly inhibited the LPS-induced neutropenia and endotoxic shock in the rats.

See title; abstract; Materials and Methods; Results; and page 6563.

Claims 26-28 are anticipated by Strachan *et al.*

15) Claims 26-28 are rejected under 35 U.S.C § 102(a) as being anticipated by Huber-Lang *et al.* (*The FASEB J.* 16: 1567-1574, October 2002).

Huber-Lang *et al.* taught a method of treating sepsis in mice suffering from sepsis by providing a small molecule cyclic peptide antagonist reagent, C5aRa, to the C5a receptor (C5aR) and administering the reagent to the septic mice. The treatment diminished the C5a-dependent inflammatory lung injury symptom and greatly improved the mice survival. Huber-Lang *et al.* taught that C5aRa reagent blocks C5aR in sepsis. See abstract; pages 1567 and 1571; and Figures 5 and 6.

Claims 26-28 are anticipated by Huber-Lang *et al.*

16) Claims 26, 27 and 30 are rejected under 35 U.S.C § 102(b) as being anticipated by Larrick *et al.* (EP 0 245 993 A2) as evidenced by Huber-Lang *et al.* (*The FASEB J.* 16: 1567-1574, October 2002).

Larrick *et al.* disclosed a method comprising providing a therapeutic monoclonal anti-C5a antibody reagent which blocks the specific binding to the C5a complement component or neutralizes the C5a complement component, and administering the antibody to a mammalian patient for treatment of sepsis. See abstract; and pages 3-5. That the administration of the prior art anti-sepsis anti-C5a antibody therapeutic reagent results in a decrease in symptoms of sepsis is inherent from the teachings of Larrick *et al.* in light of what is well known in the art. For instance, Huber-Lang *et al.* showed that a C5a receptor antagonist diminishes symptoms of sepsis. See abstract; pages 1567 and 1571; and Figures 5 and 6 of Huber-Lang *et al.*

Claims 26, 27 and 30 are anticipated by Larrick *et al.* The reference of Huber-Lang *et al.* is **not** used as a secondary reference in combination with the reference of Larrick *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Larrick *et al.* with the unrecited limitation(s) being inherent as evidenced by the state of the art. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Relevant Prior Art

17) The following reference, not applied in any of the rejections currently, is pertinent to the

subject matter of the invention.

- Short *et al.* (*Br. J. Pharmacol.* 125: 551-554, 1999 - Applicants' IDS) demonstrated the dose-dependent antagonism of LPS-induced neutropenia in a rat model of acute endotoxic shock by therapeutic administration of a new small molecule C5a receptor antagonist, the cyclic peptide Phe-[Orn-Pro-dCha-Trp-Arg], or F-[OPdChaWR]. See title; abstract; Methods; and Results.

Remarks

18) Claims 26-28 and 30 stand rejected.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives facsimile transmissions 24 hours a day and 7 days a week.

20) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

21) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

SD

S. DEVI, PH.D.
PRIMARY EXAMINER

January, 2007